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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,446	04/17/2001	Eugene C. Butcher	STAN110CON	4334
24353	7590	09/13/2004	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 University Ave East Palo Alto, CA 94303			MERTZ, PREMA MARIA	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 09/13/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/837,446	BUTCHER ET AL.	
	Examiner	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-28,30,31 and 33-38 is/are pending in the application.
- 4a) Of the above claim(s) 33,34 and 36-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-25,27,28,30,31 and 35 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/10/2004 has been entered.
2. Receipt of applicant's arguments and amendments filed on 7/29/2004 are acknowledged.
3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 7/29/2004:
 - (i) the rejection of claims 23-28, 30-31, 35 under 35 USC 112, first paragraph.
4. Applicant's arguments filed on 7/29/2004 have been fully considered but were persuasive in part. The issues are re-stated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-35 USC § 103

6. Claims 23-25, 27-28, 30, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wells et al. (U.S. Pat. No. 6,150,132) in view of Heath et al. (J. Clin. Invest. 1997; 99:178-184).

This rejection is maintained for reasons of record set forth at pages 12-13 of the previous Office action (7/7/03) and pages 4-6 of the previous Office action (6/8/2004).

Applicants argue that at the time of filing of the instant invention, one of skill in the art would not have combined Wells and Heath to provide a method of inhibiting histamine release from basophils because Wells suggestion to modulate histamine release from basophils using a CCR4 antagonist was taught away from at the time of filing of the instant application. Applicants also argue that it is well known that CCR3 and not CCR4 is the receptor that mediates histamine release from basophils, and, accordingly, Wells and Heath could not be combined to produce a method of inhibiting histamine release using a CCR4 antagonist with any reasonable expectation of success. Well's disclosure concludes that MCP-1, MCP-1a and RANTES are ligands for CCR4 and that antagonists of CCR4 may be used to reduce histamine release from basophils. However, Applicant's point out that Imai et al (1997) and others refuted Wells observations because CCR4 is a receptor for TARC and MDC, not MCP-1, MIP-1a or RANTES. Therefore, CCR3 is the receptor that triggers histamine release from basophils. Contrary to Applicants' arguments, Wells had the right receptor but not the right ligand for the receptor. Wells may not have known the right ligands but Wells postulated correctly that the identified antagonists for CCR4 would have blocked a function of CCR4 and that such antagonists are useful in treating atopic dermatitis. Wells also teach assays for detecting binding of an agent to the K5.5(CCR4) receptor (column 2, especially lines 10-33).and that an agent that is an antagonist (i.e., a CCR4 antagonist) may be identified by the ability of the agent to block the release of histamine from basophils (bridging paragraph of columns 1-2). Therefore, from the teachings of Wells, antagonists of CCR4 would have worked to inhibit histamine release from basophils.

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Furthermore, all three basic criteria to establish a prima facie case of obviousness are met by the Wells reference. (see MPEP 1242). There is a suggestion or motivation in the Wells reference to use CCR4 antagonists that block a function of CCR4, a reasonable expectation of success as demonstrated from the Wells reference and the prior art references (Wells and Heath) when combined suggest all the claim limitations. Wells had the right concept of using CCR4 antagonists encompassing CCR4 antibodies and therefore suggested the steps of the instant method.

Applicants' arguments may be persuasive with respect to a method encompassing the species of ligand, TARC, and that the antibody inhibits binding of CCR4 to TARC. Note that the rejection has been withdrawn over claim 26 drawn to a species of ligand but has been maintained over the generic claims.

7. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wells et al. (U.S. Pat. No. 6,150,132) in view of Heath et al. (J. Clin. Invest. 1997., 99: 178-184) as applied to claims 23-28, 30 and 35 above, and further in view of Bendig (Methods: A Companion to Meth. Enzymol. 1995, 8:83-93).

This rejection is maintained for reasons of record set forth at pages 13-14 of the previous Office action (7/7/03) and pages 6-7 of the previous Office action (6/8/2004).

Applicants argue that Wells and Heath are deficient in that they fail to suggest the claimed method. However, contrary to Applicants' arguments, in paragraph 6 above, the Examiner has set forth arguments showing that Wells and Heath render obvious the claimed method. Furthermore, Bendig teaches humanized antibodies to antigens of interest since humanized antibodies are less immunogenic, have a longer half life and have more effective effector functions than rodent monoclonal antibodies when used in

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humans (see page 83, column 2). Therefore, the ordinary artisan at the time of the invention, would have had a reasonable expectation of producing humanized anti-CCR4 antibodies to be used in the claimed process as taught by Wells in view of Heath and Bendig.

Conclusion

No claim is allowable.

Claim 26 is objected to as being dependent upon a rejected base claim 23, but would be allowable if rewritten in independent form including all the limitations of base claim 23 and any intervening claims.


Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
August 23, 2004